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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,957	01/02/2001	David Shiuan	101198-3	9947
24504	7590	06/28/2005	EXAMINER	
THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/752,957

Applicant(s)

SHIUAN, DAVID

Examiner

Kathleen M. Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 11-14 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on July 10, 2003), Applicants filed a response and amendment received on November 3, 2003. Applicant's subsequent responses amended the sequence listing. Said amendment cancelled Claim 9 and amended Claims 8, 10, and 12-14. Thus, Claims 1-8 and 10-16 are pending in the instant Office action.

2. The Examiner notes that the markings to show changes in the amendment to Claims 8 and 12 are not entirely reflective of the previously pending claims.

Election

3. As previously noted, Applicant's election with traverse of Group II, Claims 8-14, in Paper No. 12 is acknowledged. The elected Group is drawn to method claims, thus, no rejoinder is applicable. Claims 8 and 10-14 are drawn to the elected invention and will be examined herein. Claims 1-7 and 15-16 remain withdrawn from consideration as non-elected inventions.

This application contains claims 1-7 and 15-16 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection **must** include cancellation of nonelected claims or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

Priority

4. As previously noted, the instant application is granted the benefit of priority for the foreign application 89120972 filed in Taiwan on October 7, 2000.

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As previously noted, receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. A certified translation of said document was received on November 3, 2003.

Compliance with the Sequence Rules

5. The substitute sequence listing filed in computer readable form and in paper copy on March 10, 2005 containing 5 sequences has been entered. By virtue of said sequence listing and an amendment to the specification, the instant application now fully complies with the sequence rules.

Withdrawn - Objections to the Specification

6. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title as suggested by the Examiner.

7. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.

8. Previous objection to the specification for inconsistencies and/or confusing subject matter is withdrawn for all points except one (see below) by virtue of Applicant's amendment.

New or Maintained - Objections to the Specification

9. Previous objection to the specification for being confusing on page 12, lines 13-14 is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the 233 sequence is complete and the 204 sequence

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is a truncated version having the same activity. While this may be true, this is still unclear since SEQ ID NO:1 is 1188 base pairs encoding a 396 amino acid protein. Thus, it is unclear how only a 233 sequence can be considered "complete". Clarification is required.

10. The amendment filed November 3, 2003 is objected to under 35 U.S.C. § 132(a) because it introduces new matter into the disclosure. 35 U.S.C. § 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- a) Changing the WT biotin production in YPD from 26 ng/ml as found in Table 1 to 31.2 ng/ml is considered new matter. This same amendment is on page 14, line 24, as well.
- b) Changing of the OD in Table 1 from OD_{660 nm} to OD_{550 nm} is neither marked in the amendment nor supported in the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Withdrawn - Objections to the Claims

11. Previous objection to Claims 8-14 for depending on a non-elected claim is withdrawn by virtue of Applicant's amendment.

New - Objections to the Claims

12. Claim 10 is objected to for depending from a rejected claim. Claim 10 should depend from Claim 8. Correction is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

13. Previous rejection of Claims 8-14 under 35 U.S.C. § 112, second paragraph, as being indefinite for the relative term “high” is withdrawn by virtue of Applicant’s amendment.
14. Previous rejection of Claims 8-14 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “integrated” is withdrawn by virtue of Applicant’s amendment to an “integrating plasmid” which clearly has structural ramifications on the plasmid claimed in the method.
15. Previous rejection of Claims 8-14 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “assistant DNA sequence for the integration of said plasmid into a host genome” is withdrawn by virtue of Applicant’s amendment to the claim to include a clear function of the “assistant DNA”. While the term “assistant” is not a term of art and is recommended to be deleted from the claim, with Applicant’s clarification on the record and the definition in the claim itself, the term is not so unclear as to rise to the level of rejection under 35 U.S.C. § 112, second paragraph. As previously noted, a good reference is the enclosed Stearns *et al.* who teach the use of URA3 and HIS3 markers for integration.
16. Previous rejection of Claims 9-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “derived from” is withdrawn by virtue of Applicant’s amendment and/or cancellation of said claims.

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17. Previous rejection of Claim 10 under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of “gene of *Candida utilis*” is withdrawn by virtue of Applicant’s amendment.

18. Previous rejection of Claim 11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “NsiI-BamHI 18s rDNA” is withdrawn by virtue of the Examiner’s reconsideration as it has been identified that this fragment is a particular fragment of the *C. utilis* genome.

19. Previous rejection of Claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “cycloheximide-resistant gene” is withdrawn by virtue of Applicant’s amendment.

20. Previous rejection of Claim 13 under 35 U.S.C. § 112, second paragraph, as being indefinite for the promoters “pL41” and “pADH1” is withdrawn by virtue of Applicant’s amendment.

21. Previous rejection of Claim 14 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “useful as feed additives, food additives, or cosmetics” is withdrawn by virtue of the Examiner’s reconsideration.

New - Claim Rejections - 35 U.S.C. § 112

22. Claims 8 and 11-14 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Although the genus of any biotin synthase gene is adequately described by virtue of its being well-known in the art, the particular subgenus in Claim 8 of a *C. utilis* biotin synthase gene, wherein said subgenus is larger than merely SEQ ID NO:1 by virtue of the further limiting nature implied in Claim 10, lacks adequate written description.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification discloses one species of a *C. utilis* biotin synthase gene in SEQ ID NO:1. No discussion of general *C. utilis* genes is provided (i.e., codon usage, etc.). While the broader genus of any biotin synthase gene is adequately described, no particular features of *C. utilis* biotin synthase genes are described, either structurally or functionally, except for the single species disclosed. Thus, one of skill in the art would be unable to identify members of the claimed genus.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

23. Previous rejection of Claims 8-10 and 14 under 35 U.S.C. § 102(b) as being anticipated by Pearson *et al.* (GB 2216530A, see PTO-892) as evidenced by Stearns *et al.* (see PTO-892) is

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withdrawn by virtue of Applicant's amendment clearly requiring the *C. utilis* biotin synthase gene be used in the claims. This is not taught by Pearson *et al.*

The Examiner does not, however, that Applicant's arguments concerning using more than one reference in a rejection under 35 U.S.C. § 102 are unfounded. Supporting references evidencing facts may be used in rejections under 35 U.S.C. § 102 (see M.P.E.P. § 2131.01).

Withdrawn - Claim Rejections - 35 U.S.C. § 103

24. Previous rejection of Claims 8-10 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Pearson *et al.* in view of Stearns *et al.* and Hong *et al.* (GenBank Accession Number AF212161, publicly available December 7, 2000) is withdrawn by virtue of Applicant's filing of a certified translation which discloses the claimed invention. Thus, the effective filing date of the instant claims is October 7, 2000 rendering Hong *et al.* not available as prior art.

25. Previous rejection of Claims 8-10 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Pearson *et al.* in view of Stearns *et al.* and Zhang *et al.* is withdrawn by virtue of Applicant's amendment excluding using *S. cerevisiae* biotin synthase gene in the claimed invention.

26. Previous rejection of Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Pearson *et al.* in view of Stearns *et al.* and Rodriguez *et al.* (Development of an integrative DNA transformation system for the yeast *Candida utilis*. FEMS Microbiol Lett (1998) 165(2): 335-340) is withdrawn by virtue of the amended claim excluding *E. coli* biotin synthase from the claimed genus.

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27. Previous rejection of Claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Pearson *et al.* in view of Stearns *et al.* and Kondo *et al.* (see IDS) is withdrawn by virtue of the amended claim excluding *E. coli* biotin synthase from the claimed genus.

Summary of Pending Issues

28. The following is a summary of the issues pending in the instant application:

- a) Claims 1-7 and 15-16 are non-elected inventions still pending, requiring cancellation in response to the instant Final rejection.
- b) The specification stands objected to for being confusing on page 12, lines 13-14.
- c) The amendment filed November 3, 2003 stands objected to under 35 U.S.C. § 132(a) because it introduces new matter.
- d) Claim 10 stands objected to for depending from a rejected claim.
- e) Claims 8 and 11-14 are rejected under 35 U.S.C. § 112, first paragraph, written description

Conclusion

29. Claims 8 and 11-14 are rejected; Claim 10 is objected to. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

June 22, 2005